

B6
53. A preparation as claimed in claim 53, wherein said tissue-promoting factor is a fragment thereof wherein said fragment retains biological activity.

Please admit the following new claims:

B7
54. (New) A preparation as claimed in claim 40, wherein the weight ratio between lipid and water or some other water-based liquid is in the order of 3:2 to 4:1.

55. (New) A preparation as claimed in claim 31, wherein said glycoamineoglycan comprises hyaluronic acid.

REMARKS

Status of Claims:

Claims 31-53 were pending in the application; claims 54 and 55 are hereby added by amendment. Claims 31-55 are now pending. Each of the pending claims defines an invention that is novel and unobvious over the cited art. Favorable consideration of this case is respectfully requested.

Claim Objections:

Claims 45-50 were objected to as depending from a cancelled claim. Claim 45 is hereby amended to depend from claim 31.

Rejections Under 35 U.S.C. § 112, 2nd Paragraph:

Claims 31-44, and 51-53 were rejected under 35 U.S.C. § 112, 2nd Paragraph, as being indefinite. Claim 31 was objected to for numerous instances of informal recitations rendering the claim indefinite. Claim 31 is hereby amended to correct the informal language. Claim 44 and 52 were deemed to be indefinite for recitations of "it." Claims 44 and 52 are hereby amended to specify the element to which the recitation "it" referred. Claims 32-43, 51, and 53 were rejected for depending from a rejected base claim. The instant amendment should operate to render claim 31 allowable and therefor, render moot this ground of rejection.

Rejection Under 35 U.S.C. § 102(b)/(e):

Claims 31, 39-42, 54-47, and 51 were rejected under 35 U.S.C. § 102(b) as being anticipated by Larsson (5,196,201).

Rejection under 35 U.S.C. § 102 requires the prior art disclose each and every limitation of the claimed invention (MPEP § 706.02). In determining anticipation, no claim limitation may be ignored. See *Pac-Tex, Inc. v. Amerace Corp.*, 14 USPQ2d 1871 (Fed. Cir. 1990). Anticipation requires the disclosure, in a prior art reference, of each and every recitation as set forth in the claims. See *Titanium Metals Corp. v. Banner*, 227 USPQ 773 (Fed. Cir. 1985), *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986), and *Akzo N.V. v. U.S. International Trade Commissioner*, 1 USPQ2d 1241 (Fed. Cir. 1986). There must be no difference between the claimed invention and reference disclosure for an anticipation rejection under 35 U.S.C. § 102. See *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001 (CAFC 1991) and *Studiengesellschaft Kohle GmbH v. Dart Industries*, 220 USPQ 841 (CAFC 1984). The evidentiary record fails to teach each limitation of the present invention in view of the silence of Larsson regarding the inclusion of hyaluronate. ← in amendment old claim 43-44

Claims 31, 39-42, 54-47, and 51 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bauer (5,338,772). The evidentiary record fails to teach each limitation of the present invention in view of the silence of Bauer regarding the inclusion of hyaluronate and/or phosphoglycerides.

Claims 31, 36, 38, 40, 45-48, and 50 were rejected under 35 U.S.C. § 102(b) as being anticipated by NGK Spark Plug. NGK is silent as to hyaluronic acid.

Claims 31, 43-44, 52, and 53 were rejected under 35 U.S.C. § 102(e) as being anticipated by Cassidy (6,280,474).

The specification is hereby amended to claim the priority of PCT/SE99/01231, filed July 6, 1999, which in turn, claims the priority of Sweden 9802529-9, filed July 13, 1998. Cassidy issued August 28, 2001 based on a filing date of July 27, 1999. The present application was filed prior to Cassidy and therefore, Cassidy is disqualified as a reference.

Rejection Under 35 U.S.C. § 103(a):

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it's Jan 8, 1998
or
possibly
April 10, 1997
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Claims 32-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bauer in view of Haynes (5,972,366).

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*. All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*. (MPEP § 2143.03). When evaluating the scope of a claim, every limitation in the claim must be considered. See e.g. *In re Ochiai*. (MPEP § 2144.08). The evidentiary record fails to teach each limitation of the present invention. Specifically, the references taken as a whole or severally fail to teach hyaluronate.

Conclusion:

In view of the above, consideration and allowance are, therefore, respectfully solicited.

Accordingly, it is respectfully requested that the foregoing amendments be entered, that the application as so amended receive an examination on the merits, and that the claims as now presented receive an early allowance.

In the event the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this communication, including any extension fees or fees for the net addition of claims, to Deposit Account No. 22-0185.

Respectfully submitted,



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APPENDIX

(Amendments with markings to show changes)

IN THE SPECIFICATIONS:

Please amend the specifications as follows:

On page 1, before the first sentence, insert the following section:

REFERENCE TO RELATED APPLICATION

-- This Application is a 371 of PCT/SE99/01231, filed 07/06/99, which in turn claims the priority of Sweden 9802529-9 filed 13 July 1998.--

IN THE CLAIMS:

Please cancel claims 1-30 and add the following new claims.

31. (Amended) A bioresorbable and biocompatible composition for restoring bone in the body of a human or other animal in need thereof, said composition comprising:

calcium phosphate granules; ← Hydroxapatite, tricalcium phosphate

lipid;

hyaluronic acid; and

at least one phosphoglyceride, wherein said composition forms a moldable mass upon

admixture with water. [A preparation for restoring bone in the body of humans or animals in connection with an existing structure, a bone implant or some other prosthetic construction, the preparation being intended to be applied in the position in connection with, for instance, a bone implant or some other prosthetic construction where there is a lack of sufficient bone volume, or where the quality of the bone is too poor, or to allow a load-carrying function, said preparation being an easily handleable, controllable and decomposable carrier preparation of calcium phosphate granules or a biological organic component of a biopolymer and/or lipid type wherein the preparation at its application has a moldable consistency by admixed water or some other water-based liquid, such as body fluid.]

40. (Amended) A preparation as claimed in claim 31, wherein the lipid consists of at least one phospholipid and [water or some other] a water-based liquid as carrier.

42. A preparation as claimed in claim 40, wherein the weight ratio between lipid and water or some other water-based liquid is in the order of 1:2 to 10:1[, preferably 3:2 to 4:1].

43. (Amended) A preparation as claimed in claim 31, [wherein the biopolymer contains a] further comprising glycoaminoglycan[, for example hyaluronic acid].

44. (Amended) A preparation as claimed in claim 43, wherein [it] said preparation consists of a free-flowing mixture of sodium hyaluronic acid and calcium phosphate granules which can be packed and then rehydrated in connection with use.

45. (Amended) A preparation as claimed in claim [30] 31, wherein the calcium phosphate granules have a Ca/P ratio which is between 1 and 2.

47. (Amended) A preparation as claimed in claim 45, wherein the calcium phosphate [contains] is selected from the group consisting of dicalcium phosphate dihydrate, octacalcium phosphate, tricalcium phosphate and[/or] hydroxyapatite.

48. (Amended) A preparation as claimed in claim 45, wherein the calcium phosphate [contains] further comprises materials selected from the group consisting of magnesium, fluorine [or] and carbonate ions.

New Matter
52. (Amended) A preparation as claimed in claim 31, [wherein it contains] further comprising biologically-active factors selected from the group consisting of tissue-promoting factors, [and/or] factors which inhibit decomposition of tissue, [for example a] and growth factors [factor, such as BMP and TGF beta or parts thereof].

53. A preparation as claimed in claim [31] 53, wherein [the] said tissue-promoting factor is [added wholly or partially] a fragment thereof wherein said fragment retains biological activity.

New Matter

PTO/SB/97 (08-00)

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Amendment Under 37 CFR 1.111. Eight (8) pages.

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